BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

NOTICE OF MEETING AND AGENDA Enforcement and Compounding Committee December 11, 2017

DATE: December 11, 2017

TIME: 9:30 a.m.

PLACE: Department of Consumer Affairs

First Floor Hearing Room 1625 North Market Blvd Sacramento, CA 95834

WEBCAST: https://thedcapage.wordpress.com/webcasts/

(Webcast will be available earliest at 9:30 a.m. on December 11, 2017. See notices below.)

NOTE: Pharmacists and pharmacy technicians who attend in person may be awarded 2 hours of continuing education (CE), in accordance with the Board's CE regulation. Sign in and sign out on the day of the meeting will be required for the CE credit.

For verification of the meeting, call (916) 574-7918 or (916) 574-7900 or access the Board's Web site at www.pharmacy.ca.gov.

Meeting materials should be available on the Board's Web site at www.pharmacy.ca.gov by December 7, 2017.

The meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Laura Hendricks at (916) 574-7918, by emailing laura.hendricks@dca.ca.gov or sending a written request to the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Discussion and action may be taken on any item on the agenda. The time and order of agenda items are subject to change at the discretion of the Committee Chairperson and may be taken out of order. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board are open to the public. The board plans to webcast this meeting at the link provided above. Webcast availability cannot, however, be guaranteed due to limited resources or technical difficulties. The meeting will not be cancelled if the webcast is not available. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend a the physical location.

*Government Code Section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the committee or prior to the committee taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issues before the committee, but the Committee Chairperson may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before the committee to discuss items not on the agenda; however, the committee can neither discuss nor take official action on these items at the time of the same meeting (Government Code Sections 11125, 11125.7(a)).

Agenda

Call to Order 9:30 a.m.

- 1. Call to Order and Establishment of Quorum
- 2. Public Comment for Items Not on the Agenda, Matters for Future Meetings*

 *Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a)
- 3. Discussion and Consideration of Possible Statutory Proposal Relating to the Use of Automated Drug Delivery Systems (ADDS)
- 4. Discussion and Consideration of Possible Board Policy Relating to Disclosure of Enforcement Actions Involving Board Members
- 5. Discussion and Consideration of FDA Draft Guidance for Industry Relating to "Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier"
- 6. Discussion and Consideration of "CURES 2.0 Survey of California Physicians' and Pharmacists' Experience with and Attitudes about CURES 2.0"
- 7. Discussion and Consideration of Possible Statutory Proposal to Require E-Prescribing of Prescription Drugs
- 8. Discussion and Consideration of Noncompliant California Security Prescription Forms
- 9. Update on Emergency Regulations to Amend California Code of Regulations, Title 16 Section 1735.2, Related to Compounding Beyond Use Dates
- 10. Discussion and Consideration of Draft Frequently Asked Questions Relating to Compounding Requirements, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq.
- 11. Discussion and Consideration of Requested Changes to Board Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq., Including Presentation Regarding Beyond Use Date Testing
- 12. Status Reports on Waivers Issued for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6 and 1751.4
- 13. Enforcement Statistics
- 14. Future Committee Meeting Dates

Adjournment